

ITHS Clinical Research Education Series

Innovations in Informed Consent

June 20, 2017

Takeaways from Randomization Discussion to Enhance Informed Consent Comprehension

The group came up with several creative ways to present information about randomization and placebo and also to test participants' understanding.

1. Use of visuals

- a. Flowcharts showing study arms, with numbers of participants in each arm
- b. Pictures of metaphors
 - i. Flipping a coin
 - ii. Choosing numbers out of a hat
 - iii. Rolling a die
 - iv. Picture of a patient sitting at a computer that is making choices
 - v. Placebo as decaf coffee & study drug as caffeinated coffee
 - vi. Picking M&Ms of different colors while blindfolded

2. Clarifying language

- a. Provide definitions of terms (e.g., placebo = sugar pill)
- b. Eliminate any unnecessary language (e.g., number of participants in each arm)
- c. Shorter sentences, use of plain language

3. Explaining more about randomization that is relevant to the decision

- a. Unblinding will occur if participant has serious adverse event

4. Active participation to make the concepts make sense

- a. Have potential participants act out a skit with multiple coordinators demonstrating assignments to different arms, and taking steps to make sure the decision stays blinded
- b. Have potential participants use playing cards to hypothetically assign others to receive the intervention or placebo

5. Test/feedback approach with specific questions

- a. True/false questions (e.g., there is a chance I will receive placebo?)
- b. Open-ended questions or "teachback" approach to ask participants what they understand and correct misunderstandings